K002239

AUG 8 2000

Kontron Medical S.A.S
510(k) Submission
Sigma 110/330 Ultrasound Systems

510(k) Summary

June 5, 2000

(1) Submitter Information

Name: Kontron Medical S.A.S.
Address: 52, rue Pierre Curie
78370 Plaisir
France
Manufacturing Address: Same
Telephone: +33 1 30 57 66 00
Contact Person: Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Rt. 17 S
Hasbrouck Heights, NJ 07604
201-727-1703
Fax 201-727-1708

Date Prepared: June 5, 2000

(2) Name of Device:

Trade Name: Sigma 110/330 Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound System and Probes

Classification Name: (a) System, Imaging, Pulsed echo, Ultrasonic 90 IYO
(b)Transducer, Ultrasonic, Diagnostic, 90 ITX

(3) Equivalent Legally-Marketed Devices:
GE Logiq 500, K953752

The technological characteristics of the predicate device are the same as those of the ew device.

(4) Description

The "Sigma 110 / 330" is a small, modular ultrasound instrument intended to perform the following diagnostic ultrasound investigations: Imaging (B-mode), Time motion (TM-mode), Pulsed wave Doppler (PW Doppler), Continuous wave Doppler (CW Doppler) and Color Flow Mapping (CFM). CFM is only possible in conjunction with electronically scanned transducers on the Sigma 330 systems.
This submission also includes the transducers necessary for these procedures.

(5) Intended Use

Diagnostic ultrasound investigations including: Imaging (B-mode), Time motion (TM-mode), Pulsed wave Doppler (PW Doppler), Continuous wave Doppler (CW Doppler) and Color Flow Mapping (CFM).

(6) Performance Data

(a) Non-clinical tests

The Sigma 110/330 devices have succesfully passed IEC 601-1 (electrical safety) and IEC 601-1-2 (electromagnetic compatibility), biocompatibility tests for patient contact materials, and accuracy tests for all biocompatibility modes, as well as software validation tests.

(b) Clinical Tests

Since the Sigma 110/330 uses the same technology and principles as existing devices, clinical tests are not required. However, a clinical demonstration showing the images obtainable on the different modes is also presented.

(c) Conclusion

The Sigma 110/330 Ultrasound sysytem with the associated tansducers is equivalent in safety and efficacy to the legally-marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 8 2000

Kontron Medical Systems S.A.S.
c/o CITECH
Mr. Robert Mosenkis
President
Medical Device Testing and Consulting
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K002239
Sigma 110/330 Diagnostic Ultrasound System
Regulatory Class: II
21 CFR §892.1550/Procode: 90 IYN
21 CFR §892.1560/Procode: 90 IYO
Dated: July 21, 2000
Received: July 24, 2000

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the transducers listed below intended for use with the Sigma 110/330 Diagnostic Ultrasound System as described in your premarket notification.

3.5 MHz CV	5.0 MHz CUR	5.0 MHz LIN
7.5 MHz LV	7.5 MHz LVS	7.5 MHz LVD
6.5 MHz VMC	6.5 MHz EV	6.5 MHz MR
3.5 MHz GP	3.5 MHz GPD	3.5 MHz GL
5.0 MHz GP	5.0 MHz GL	7.5 MHz GP
7.5 MHz GL	14 MHz PV	2 MHz TCD
2 MHz PEN	4 MHz PEN	8 MHz PEN

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further

announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Mr. Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

1.3 Indication for use

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N	N	N	N			
Abdominal		N	N	N	N	N	N			
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N			
Small organs (specify)		N	N	N	N	N	N			
Neonatal Cephalic		N	N	N	N	N	N			
Adult Cephalic		N	N	N	N	N	N			
Cardiac		N	N	N	N					
Transesophageal										
Transrectal		N	N	N		N	N			
Transvaginal		N	N	N		N	N			
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N			
Laparascopic										
Musculo-skeletal Conventional		N	N	N	N	N	N			
Musculo-skeletal Superficial		N	N	N	N	N	N			
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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.....Color Doppler & Amplitude Doppler only on Sigma 330 Systems
Small organs: Thyroid, Breast, Testicle

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

✓ Prescription Use (Per 21 CFR 801.109)

510(k) Number K002239

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 3.5 MHz CV**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N			
Abdominal		N	N	N		N	N			
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N			
Small organs (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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.....Color Doppler & Amplitude Doppler only on Sigma 330 Systems

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

✓ Prescription Use (Per 21 CFR 801.109)

510(k) Number K002239

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 5.0 MHz CUR**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N						
Abdominal		N	N	N						
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N						
Small organs (specify)		N	N	N						
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional		N	N	N						
Musculo-skeletal Superficial		N	N	N						
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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.....Color Doppler & Amplitude Doppler only on Sigma 330 Systems
Small organs: Thyroid, Breast, Testicle

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Clayman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K002239

✓ Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 5.0 MHz LIN**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N						
Abdominal		N	N	N						
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N						
Small organs (specify)		N	N	N						
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional		N	N	N						
Musculo-skeletal Superficial		N	N	N						
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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.....Color Doppler & Amplitude Doppler only on Sigma 330 Systems
Small organs: Thyroid, Breast, Testicle

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Clegorn

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K002239

✓ Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 Transducer: 7.5 MHz LV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N			
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N			
Small organs (specify)		N	N	N		N	N			
Neonatal Cephalic		N	N	N		N	N			
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N			
Laparascopic										
Musculo-skeletal Conventional		N	N	N		N	N			
Musculo-skeletal Superficial		N	N	N		N	N			
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:..

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........Color Doppler & Amplitude Doppler only on Sigma 330 Systems
Small organs: Thyroid, Breast, Testicle

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002239

✓ Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 7.5 MHz LVS**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N			
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N			
Small organs (specify)		N	N	N		N	N			
Neonatal Cephalic		N	N	N		N	N			
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N			
Laparascopic										
Musculo-skeletal Conventional		N	N	N		N	N			
Musculo-skeletal Superficial		N	N	N		N	N			
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix ~~E~~

Additional Comments:.....

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.....Color Doppler & Amplitude Doppler only on Sigma 330 Systems
Small organs: Thyroid, Breast, Testicle

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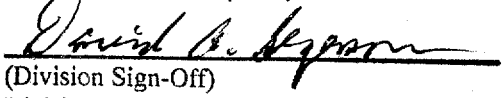
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, **ENT,** and Radiological Devices

510(k) Number K002239

✓ Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 7.5 MHz LVD**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N			
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N			
Small organs (specify)		N	N	N		N	N			
Neonatal Cephalic		N	N	N		N	N			
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N			
Laparascopic										
Musculo-skeletal Conventional		N	N	N		N	N			
Musculo-skeletal Superficial		N	N	N		N	N			
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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.....Color Doppler & Amplitude Doppler only on Sigma 330 Systems
Small organs: Thyroid, Breast, Testicle

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legeron

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K002239

✓Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 Transducer: 6.5 MHz VMC

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N			
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organs (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N			
Transvaginal		N	N	N		N	N			
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:..

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........Color Doppler & Amplitude Doppler only on Sigma 330 Systems

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002239

✓ Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 6.5 MHz EV**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N						
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organs (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N						
Transvaginal		N	N	N						
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hegmon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

✓ Prescription Use (Per 21 CFR 801.109)

510(k) Number K002239

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 6.5 MHz MR**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organs (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N						
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K002239

✓ Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 3.5 MHz GP**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N	N					
Abdominal		N	N	N	N					
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organs (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legenon

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K002239

✓ Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 3.5 MHz GPD**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N	N					
Abdominal		N	N	N	N					
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organs (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002239

✓ Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 3.5 MHz GL**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N	N					
Abdominal		N	N	N	N					
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organs (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legassa

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

✓ Prescription Use (Per 21 CFR 801.109)

510(k) Number K002239

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 5.0 MHz GP**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N	N					
Abdominal		N	N	N	N					
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N					
Small organs (specify)		N	N	N	N					
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional		N	N	N	N					
Musculo-skeletal Superficial		N	N	N	N					
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Jeppson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

✓ Prescription Use (Per 21 CFR 801.109)

510(k) Number K002239

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 5.0 MHz GL**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N	N					
Abdominal		N	N	N	N					
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N					
Small organs (specify)		N	N	N	N					
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional		N	N	N	N					
Musculo-skeletal Superficial		N	N	N	N					
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hoyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K002239

✓ Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 7.5 MHz GP**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N	N					
Abdominal		N	N	N	N					
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N					
Small organs (specify)		N	N	N	N					
Neonatal Cephalic		N	N	N	N					
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N					
Laparascopic										
Musculo-skeletal Conventional		N	N	N	N					
Musculo-skeletal Superficial		N	N	N	N					
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segner

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

✓ Prescription Use (Per 21 CFR 801.109)

510(k) Number K002239

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 7.5 MHz GL**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N	N					
Abdominal		N	N	N	N					
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N					
Small organs (specify)		N	N	N	N					
Neonatal Cephalic		N	N	N	N					
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N					
Laparascopic										
Musculo-skeletal Conventional		N	N	N	N					
Musculo-skeletal Superficial		N	N	N	N					
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David B. Jeppson

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K002239

✓ Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 14 MHz PV**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N						
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N						
Small organs (specify)		N	N	N						
Neonatal Cephalic		N	N	N						
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N						
Laparascopic										
Musculo-skeletal Conventional		N	N	N						
Musculo-skeletal Superficial		N	N	N						
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Jegerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002239

✓ Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 Transducer: 2 MHz TCD

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organs (specify)										
Neonatal Cephalic										
Adult Cephalic				N						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:...

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002239

✓ Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 2 MHz PEN**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organs (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac				N	N					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hoffman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K002239

✓ Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 4 MHz PEN**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organs (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				N	N					
Laparascopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K002239

✓ Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330 **Transducer: 8 MHz PEN**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organs (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				N	N					
Laparascopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:.....

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Ferguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002239

✓ Prescription Use (Per 21 CFR 801.109)